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RESEARCH PAPER

The Multiple Sclerosis Impact Profile (MSIP). Development and testing psychometric properties of an ICF-based health measure

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Abstract

Purpose. The aim of this study was to develop and test the structure of the Multiple Sclerosis Impact Profile (MSIP), and to evaluate its reliability and validity within a large group of MS patients.

Method. Data were obtained from a postal survey of 377 patients attending the Groningen MS centre of the university hospital and 153 patients from the MS patients' association.

Results. Factor analysis showed that the MSIP comprised domains representing the four components of the International Classification (ICF). The *body functions* component comprised two factors, which we divided into three scales: 'muscles and muscle movement functions' (MMF), 'excretion and reproductive functions' (ERF) and 'mental functions' (MF). The *activities* component comprised one factor, which we divided into two scales: 'basic movement functions' (BMF) and 'activities of daily living' (ADL). The *participation* component comprised one factor: 'participation in life situations' (PLS). The *environmental factors* component comprised one factor: 'environmental factors' (EF). Four clinically relevant 'symptom' items were added to the questionnaire as single items. The MSIP scales yielded sufficient to good internal consistency coefficients. Analysis of the convergent, divergent and known-groups validity indicated that the MSIP measures the physical, psychological and social impact of MS and discriminates between categories of course of disease and disease severity.

Conclusion. The MSIP seems to be a reliable and valid ICF-based outcome measure that covers a broad range of clinically relevant aspects of health. ICF can play an important role in measurement development and improvement of a unified and standard language in clinical practice and research.

Keywords: Multiple sclerosis, Multiple Sclerosis Impact Profile, functional health outcome measurement, International Classification of Functioning Disability and Health, psychometric properties

Abbreviations: DIP, Disability and Impact Profile; SF-36, Medical Outcome Study Short Form Questionnaire; WHOQOL-BREF, World Health Organization Quality of Life-BREF; GARS, Groningen Activity Restriction Scale; IPAQ, Impact on Autonomy and Participation Questionnaire; MSIP, Multiple Sclerosis Impact Profile

Introduction

Multiple sclerosis (MS) is a chronic, demyelinating, neurodegenerative disorder of the central nervous system (CNS). The onset is usually in early adulthood. MS is often progressive and debilitating. Common symptoms include optic nerve dysfunction (e.g., visual failure); sensory disturbance (e.g., facial pain, sensory level disturbance, numbness or tingling

sensations); pyramidal tract dysfunction (e.g., increased muscle tone and hyperreflexia); ataxia (e.g., failure of muscle control in limbs resulting in a lack of balance and coordination, or a disturbance of gait); double vision; bladder and/or bowel dysfunction; and sexual dysfunction [1,2]. In addition, impairments in speech functions [3], fatigue [4], cognitive impairments [5] and depression are often indicated as relevant symptoms in MS. These

symptoms have a profound impact on daily functioning and participation in life situations.

In clinical practice and research, reliable and validated assessment tools and outcome measures are needed that cover this broad range of health problems in MS patients. The International Classification of Functioning, Disability and Health (ICF) is a classification of human functioning and disability that can be used in the development of such measures [6]. The overall aim of the ICF classification is to provide a unified and standard language and a framework for the description of health and health-related states. The ICF enables the user to record useful profiles of individuals' functioning, disability and health in various domains. The ICF comprises four key components. The first component, *body functions and structures*, refers to functions of body systems, such as 'sleep functions' or 'muscle functions', and to anatomic parts such as 'structure of brain' or 'structure of urinary system'. The second component, *activities*, refers to 'task or action execution by the individual' such as 'washing oneself', 'walking' and 'doing housework'. The third component, *participation*, refers to 'involvement in life situations' such as 'family relationships' and 'work and employment'. The *environmental factors* such as 'personal care providers' and 'transportation services', which interact with these three components, are described in the fourth component of the ICF [6].

In the model of functioning that underlies the ICF classification system, the components body functions and structures, activities and participation are summarized under the concepts 'functioning' and 'disability'. These are associated both with health status and with personal and environmental factors. Functioning is an umbrella term encompassing all body functions, activities and participation. Similarly disability is an umbrella term for impairments in *body functions* (e.g., impairment in muscle functions), limitations in *activities* (e.g., limitations in walking) and restrictions in *participation* (e.g., restriction in family relationships) [6].

The ICF in its original form with more than 1400 categories is hardly practicable in clinical practice or research. For assessment in clinical practice and treatment trials ICF-based tools are required which are tailored to the needs of the prospective users [7]. To the best of our knowledge there is no disease-specific measure for MS, based on the broad scope of the ICF. We therefore developed a questionnaire to measure disability in patients with MS, based on a selection of relevant aspects from the four ICF components [8]. We called this questionnaire the Multiple Sclerosis Impact Profile (MSIP).

The objective of this study is to develop and test the structure of the MSIP, and to evaluate the

reliability and validity of this new measure within a large group of MS patients.

The following research questions were addressed:

- (1) Which items are representative for the ICF components that are hypothesized to be relevant for MS and do these items comprise scales?
- (2) What is the reliability of these scales?
- (3) Do these scales measure MS-specific domains of functioning as they purport to do?
- (4) Do these scales discriminate between groups of subjects known to differ on clinically relevant characteristics?

Methods

Sample and procedure

We addressed our research questions with a cross-sectional multi-centre study using samples of MS patients from two studies: (i) members of the MS patients' association in the northern parts of the Netherlands (PA sample). These patients participated in a study evaluating an integrated care programme and were asked for separate consent to participate in this study, and (ii) patients from the Groningen MS centre, which is part of the Neurology Department of the University Hospital (UH sample). Eligible patients were selected from the patient record system of the hospital. Before recruiting patients from the University Hospital we meticulously removed all patients already participating in the PA study from the sampling base, to prevent patients from participating in both studies. Of the 172 questionnaires sent out in the PA sample, 153 questionnaires (89% response rate) were returned and used for analyses. Nineteen questionnaires (11%) were not returned. Of the 562 UH patients, 185 (33%) dropped out due to: (i) change of address or deceased, $n = 82$, (ii) too ill to fill out the questionnaire, $n = 9$, and (iii) 94 questionnaires were not returned. The remaining 377 patients (67% response rate) completed the questionnaires. Non responders in the PA sample did not differ in age ($t = 0.35$; $df = 20$; $p = 0.73$) and gender ($\chi^2 = 1.11$; $df = 1$; $p = ns$) from participating patients. Similar results were found in evaluating differences between non responders and patients in the UH sample (age: $t = 1.72$; $df = 95$; $p = 0.09$; gender: $\chi^2 = 0.17$; $df = 1$; $p = ns$).

Respondents in both samples completed the MSIP, the WHOQOL-BREF and demographic questions. Respondents in both samples filled out two additional questionnaires (and not all four, to prevent overloading of the respondents): respondents in the UH sample also completed the GARS

[9] and the IPAQ [10,11], while respondents in the PA sample also completed the SF-36 and the DIP [12,13].

The local university hospital Medical Ethics Committee approved the research protocols of both studies. Written informed consent from patients in both samples was obtained.

The MSIP

We developed the MSIP as an ICF-based measure to assess disability among MS patients in a disease-targeted way. First, items were selected from the complete version of the ICF by panels of patients, proxies and health professionals [8]. Secondly, these items were operationalized in order to estimate the patients' objectified opinion of the incidence and severity of a disability, and to estimate the support from relevant environmental factors:

- (1) The ICF terminology for 'disabilities' was applied when formulating the questions: impairments in *body functions*, limitations in *activities* and restrictions in *participation*.
- (2) ICF item labels were used when formulating the subject of the question (e.g., 'urination' functions instead of 'bladder' functions) to promote a unified language.
- (3) ICF codes (e.g., b280 or p920) were documented for each question.
- (4) Illustrative examples were annexed to some questions to ensure an adequate response.

As a result questions were phrased as follows:

- *Body function items*: 'Do you face impairment in your sleep functions? (b134)'

- *Activity items*: 'Do you face limitations in changing your body position? (a410)'
- *Participation items*: 'Are there obstacles in your environment that complicate your participation in work? (p850)'
- *Environmental Factor items*: 'Are social security services supportive for you? (e570)'

To record the presence and severity of a problem in functioning, we applied response scales with scoring options specified for each ICF component, based on 'qualifier' proposed by the ICF [14] (Table I):

- For the *body functions items* we applied the primary qualifier as a five-point scale indicating the presence of impairment and the degree of impairment of functioning.
- For the *activity items* we applied the capacity qualifier as a four-point scale with response options representing the need for assistive devices or personal assistance in executing a task or an action. Notably, during pre-testing it became clear that there were no equal distances between the applied response options. Therefore we decided to skip response options 3 ('another person's help is necessary') and to label the phrasing of response option 4 with score 3.
- For the *participation items* we applied the performance qualifier as a five-point scale with response options representing the presence and the degree of restriction in participation in life situations caused by obstacles in the current environment.
- For the *environmental factor items* we applied a three-point scale to denote the extent to which

Table I. Response options for each ICF component based on ICF qualifiers.

Generic scale	Body function component		Activities component		Participation component		Environmental factors component
	Impairment		Capacity limitation		Performance barrier		Facilitator
– –	9	I am not able to judge	9	Does not apply	9	Does not apply	9 Does not apply
0 No problem	0	No, not at all	0	No, not at all	0	No, not at all	0 Yes, very supportive
1 Mild problem	1	Yes, I have a mild impairment	1	Yes, but assist devices and/or adaptations <i>are not necessary</i> .	1	Yes, as a consequence I have <i>some</i> trouble with	– –
2 Moderate problem	2	Yes, I have a moderate impairment	2	Yes, but assist devices and/or adaptations <i>are necessary</i> .	2	Yes, as a consequence I have trouble with	2 Yes, somewhat supportive
3 Severe problem	3	Yes, I have a severe impairment			3	Yes, as a consequence I have <i>a lot of</i> trouble with . . .	– –
4 Complete problem	4	Yes, I have a complete impairment	3	Yes, assist devices and/or adaptations <i>and</i> another person's help are necessary.	4	Yes, as a consequence . . . is (nearly) impossible.	4 No, not supportive

an environmental factor acts as facilitator or barrier to execute tasks or actions, or to participate in life situations. Notably, considering the relevance and the presumed difficulty for patients to respond more accurately, we decided to apply a three-point scale in stead of the suggested five-point scale for this qualifier.

The preliminary questionnaire was reviewed by patients, clinicians, nurse specialists, experts on the ICF and methodologists ($n=24$) for clarity, comprehensiveness, redundancy and patient burden. A modified questionnaire was pre-tested in a random sample of three clinicians and 50 patients who were not involved in the first appraisal of the questionnaire. Unclear or ambiguous items and instructions were identified and modifications of the questionnaire were made. The final questionnaire used for psychometric evaluation in this study comprised of 44 items: *body functions* component (14 items), *activities* component (19 items), *participation* component (7 items) and *environmental factors* component (4 items).

Item reduction and scale construction

Using factor analysis we examined whether the domains, measured by the MSIP, represent the four ICF components. Principal component analysis (PCA) with Varimax rotation was performed and Communalities, Eigenvalues, Scree plots, explained variance and factor loadings were examined to determine the factor structure [15–17].

In order to create reliable domains, items were selected or rejected for scale construction according to two criteria: (i) items should correlate sufficiently (factor loading ≥ 0.50) with the expected domain in the data; and (ii) items correlating with more than one factor were considered to violate the assumption that each item should contribute exclusively to a single hypothetical factor or domain. Thus, items with dual factor loading ≥ 0.40 were eliminated from further analysis.

Single items

Since all items included in the original questionnaire were appraised as ‘very relevant’ by a large panel who selected these items from the ICF, we decided that items that could not meet the criteria of scalability should be taken into consideration for use as single indicators.

Reliability

Reliability was examined with the internal consistency coefficient Cronbach’s alpha (α) and the

mean inter-item correlation coefficient (MICC) for each scale [18,19]. Internal consistency refers to the overall degree to which the items that make up a scale are inter-correlated. However, the value of α is somewhat dependent on the number of items in the scale, whereas the degree of inter-item correlation does not have this dependency. α was considered sufficient if ≥ 0.70 [15]. Clark and Watson [19] recommended that the MICC should fall in the range of 0.15–0.50. They suggested this rather wide range because the optimal value will necessarily vary with the generality versus specificity of the target construct. If one is measuring a broad higher order construct, a MICC as low as 0.15–0.20 is probably desirable, while for a valid measure of a narrower construct, a much higher MICC (perhaps in the 0.40–0.50 range) is needed [18,19]. As Clark and Watson [19] suggest, test developers should use a target MICC depending on their aim rather than to try to achieve a particular value of α .

Missing values

The Cronbach’s α , in connection with the number of items included in the scales, was used as the criterion for restricting the number of missing data that were allowed to be replaced [20] by the mean score.

Convergent and discriminant validity

To test whether MSIP scales measure physical, psychological and social domains of functioning as they purport to measure, analysis of convergent and discriminant validity [16,17] was performed by examining the extent to which correlation values between MSIP scales and concurrent measures were consistent with hypotheses. We applied five concurrent self-report measures. The SF-36 and DIP were selected as well-known reliable and valid generic health-impact measures in MS [21]. The SF-36 [22] consists of 36 items and generates eight scales: physical functioning, role limitations caused by physical functioning, bodily pain, vitality, general health, social functioning, role limitations caused by emotional problems and mental health. For each dimension, item scores are coded, summed, and transformed on a scale from 0 (worst health) to 100 (best health). In a previous Dutch study with MS patients [23] the SF-36 showed satisfactory levels of internal consistency with Cronbach’s $\alpha = 0.69–0.93$ and test-retest reliability $r = 0.48–0.87$. In our study Cronbach’s $\alpha = 0.74–0.96$. The DIP [12,13] consists of 39 parallel questions about ‘(dis)ability’ and ‘impact’. It contains three symptom items and 36 items in five areas: mobility, self-care, communication, social activities and psychological

status. In this study only the disability scores were used since this construct is closely associated with the MSIP constructs. Item scores can range from 0 (no disability) to 10 (complete disability). Scores are summed for each domain. In a previous Dutch study with MS patients [23] the DIP showed satisfactory levels of internal consistency with Cronbach's $\alpha = 0.61 - 0.92$ and test-retest reliability $r = 0.61 - 0.86$. In our study Cronbach's $\alpha = 0.75 - 0.92$.

The WHOQOL-BREF was selected as a generic measure of quality of life with a broad scope, including environmental aspects. The WHOQOL-BREF, abbreviation version [24] was derived from the WHOQOL-100 version. It consists of 26 items in four constructs: physical health, psychological health, social relationships and environment. For each construct, item scores were coded, summed, and transformed on a scale from 0 (worst health) to 20 (best health). In a previous Dutch study [25] the WHOQOL-BREF showed satisfying levels of internal consistency with Cronbach's $\alpha = 0.66 - 0.80$. In our study Cronbach's $\alpha = 0.63 - 0.81$.

We used two domain specific measures, the GARS (covering activity aspects) and the IPAQ (covering participation aspects), to examine the strength of the disease-specific MSIP activity and participation aspects. The GARS [9] is a generic instrument to measure disability in activities of daily living (ADL) and instrumental activities of daily living (IADL). It consists of 11 ADL items and seven IADL items. A four-category response format is used, ranging from 1 (no problem in performing without help) to 4 (impossible to perform). Scores are summed for each subscale. The GARS was applied in several Dutch studies [9] and showed strong levels of internal consistency with Cronbach's $\alpha = 0.74 - 0.91$. In our study Cronbach's α was 0.95 and 0.97. The IPAQ [10,11] is a generic questionnaire focusing on person-perceived participation and autonomy. The instrument assesses two aspects of participation: (i) perceived participation, and (ii) the perceived problem. In this study the perceived participation aspect was used since this construct is closely associated with the operational definition of participation items in the MSIP questionnaire. The sub-domains are autonomy indoors, family role, autonomy outdoors and social relations. Item scores are graded on a five-point rating scale with discrete responses, ranging from 1 (very good) to 5 (very poor). Scores are summed for each domain. In a previous Dutch study with chronically ill patients [11] the IPAQ showed satisfactory levels of internal consistency with Cronbach's $\alpha = 0.81 - 0.91$ and test-retest reliability $r = 0.83 - 0.91$. In our study Cronbach's $\alpha = 0.86 - 0.94$.

Regarding convergent validity we hypothesized that the MSIP scales would have strong correlation (≥ 0.70) [26] with scales who cover the same domain in concurrent measures. For example, MSIP scales for physical health should correlate highly with the SF-36 'physical functioning scale' and the WHOQOL-BREF 'Physical Health and Autonomy' scale. To support discriminant validity we hypothesized that the MSIP scales would correlate weakly (< 0.40) with scales measuring different domains in MSIP or concurrent measures. For example, MSIP scales for physical health would correlate weakly with psychological health scales of MSIP and other measures. Finally, we hypothesized that correlations between scales from the same measure would be higher than correlations between scales from different measures because of mono-method effects.

Known-groups validity

Regarding known-groups validity [16,17], we hypothesized that the MSIP-scales should be able to discriminate with statistical significance between subgroups of respondents known to differ on relevant clinical characteristics as 'course of the disease' and 'extent of limitations'. To create such groups two self-report global questions were used:

- (1) To assess the course of the disease, we asked respondents 'How did your MS develop from onset?'. Respondents should select one of the six descriptions reflecting a disease course. Responses were used to create two groups: (a) patients with relapsing remitting MS with clearly defined relapses and periods between relapses characterized by a lack of disease progression; and (b) patients with progressive MS with slowly or rapidly continuous disease progression, with or without relapses [27]. Since these subgroups are based on self-reports, they are similar but not equivalent to distinctions in disease course made by a neurologist.
- (2) To assess the extent of limitations, respondents were asked to answer the question 'To what extent are you limited due to MS?' on a ten-point scale with a score range from 1 (not limited at all) to 10 (severely limited). Respondents were divided into two groups: a) those with a 'lower extent of limitations' (score 1-4); and b) those with a 'higher extent of limitations' (score 5-10).

To estimate the magnitude of the difference in mean scores between groups, Cohen's effect size d' (ES) [26] for unrelated samples was calculated.

Statistics

For comparison of the samples we used T-tests for continuous variables, Chi-square tests and Fisher exact test when appropriate, and difference of proportions tests [28] for comparisons with categorical variables. For group comparisons in the known-groups analysis we used one-way ANOVA analysis. Effect sizes were calculated only for statistically significant group differences ($\alpha = 0.05$) with post hoc tests (with Bonferroni correction for capitalization on chance in multiple testing). According to Cohen's thresholds [26] an ES of <0.20 indicates a trivial effect, an ES of ≥ 0.20 to <0.50 a small effect, an ES of ≥ 0.50 to <0.80 a moderate effect and an ES ≥ 0.80 a large effect. An Effect Size (ES) ≥ 0.20 reflects a clinical relevant difference [29].

Results

Samples

Characteristics of both samples are presented in Table II. Samples were similar with regards to the following characteristics: 71% were female, mean age was 50 years (SD 11), and 80% were married or had a partner. The employment status showed that 62% were partially or fully retired due to MS, and 8% had

retired due to age. Only 21% of the respondents were partially or full-time employed. Statistically significant differences between samples were found for two aspects: the number of years since receiving the MS diagnosis with an average of 11 years (SD 7) for the PA sample and 14 years (SD 8) for the UH sample; and the percentage of persons performing voluntary work, which was 10% in the PA sample and 5% in the UH sample.

Item reduction and scale construction

Factor analysis identified five factors covering the four ICF components and reduced the original 44 items to 32 items (Table III):

- Two factors within the *body functions* component explained 61.3% of the total variance and included ten items. Clinical interpretation of item content in the first factor led to the decision to subdivide this factor into two scales to be labelled 'muscle and movement functions' (MMF) and 'excretions and reproductive functions' (ERF). The second factor was labelled 'mental functions' (MF).
- One factor of the *activities* component explained 65.7% of the total variance and included thirteen items. Interpretation of this factor revealed items on two levels: activities

Table II. Characteristics of samples.

Variable	Total sample	PA sample	UH sample	<i>p</i> -value* 95% CI†	
<i>N</i>	530	153	377		
Gender					
Female (%)	375 (71)	114 (75)	261 (69)	0.24*	
Male (%)	155 (29)	39 (25)	116 (31)		
Age					
Mean (SD)	50 (11)	49 (9)	50 (12)	0.06#	
Range	23–85	32–75	23–85		
Years since MS diagnosis					
Mean (SD)	13 (8)	11 (7)	14 (8)	0.000#	
Range	1–53	2–30	1–53		
Marital status (%)					
Married/partnership	80	80	80	1.000*	
Unmarried/widowed/divorced	20	20	20		
Educational level (highest level) (%)					
Primary school/vocational training	154 (29)	42 (28)	112 (31)	–10.3	6.5
Secondary school/vocational training	210 (40)	59 (40)	151 (40)	–10.4	7.8
Higher prof. education/vocational training	131 (25)	41 (28)	90 (24)	–4.9	11.5
University	27 (5)	7 (5)	20 (5)	–4.3	4.2
Employment status (%) (<i>more answers possible</i>)					
Following a training or study programme	21 (4)	4 (3)	15 (4)	–4.3	2.8
Employment (part-time or full-time)	112 (21)	30 (20)	82 (22)	–9.2	5.9
Voluntary work (part-time or full-time)	33 (6)	15 (10)	18 (5)	4.0	11.0
(Partially) retired due to MS	327 (62)	95 (62)	232 (62)	–8.7	9.4
Housewife/househusband	164 (31)	51 (33)	113 (30)	–4.5	13.0
Retired due to age	42 (8)	9 (6)	33 (9)	–2.6	7.2

*Fisher's exact test (2-sided); #two-sample *t*-test; †Difference of proportions test (95% CI) [28].

Table III. Factor analysis* with MSIP items[†] (n = 595).

	Body functions component 61.3%		Activities component 65.7%	Participation component 54.3%	Environmental factors 40.2%
% explained variance	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
<i>Muscle and movement functions (MMF)</i>					
Impairment in:					
Muscle power functions	0.868	–			
Sensation of muscle stiffness and muscle spasm	0.847	–			
Involuntary movement functions	0.738	–			
Control of voluntary movement functions	0.813	–			
<i>Excretion and reproductive functions (ERF)</i>					
Impairment in:					
Defecation functions	0.632	–			
Urination functions	0.740	–			
Sexual functions	0.703	–			
<i>Mental functions (MF)</i>					
Impairment in:					
Thought, memory and attention functions	–	0.789			
Emotional functions	–	0.810			
Sleep functions	–	0.630			
<i>Basic movement activities (BMA)</i>					
Limitation in:					
Maintaining body position			0.793		
Changing body position			0.876		
Transferring oneself			0.875		
Hand and arm use			0.779		
Fine hand use			0.770		
<i>Activities of Daily Living (ADL)</i>					
Limitation in:					
Walking			0.778		
Washing oneself			0.888		
Caring for body parts			0.848		
Dressing			0.882		
Preparing meals			0.871		
Toileting			0.798		
Recreation and leisure			0.722		
Doing housework			0.613		
<i>Participation in Life Situations (PLS)</i>					
Restrictions in:					
Mobility				0.674	
Personal care				0.676	
Family and informal social relationships				0.697	
Employment				0.773	
Recreation and leisure				0.850	
<i>Environmental Factors (EF)</i>					
Support of:					
Immediate family					0.595
Personal care and assistance					0.542
Social security services					0.548
Health services					0.814

*Principal component analysis and Varimax rotation within ICF components; [†]Original 44-item version of the MSIP.

which can be labelled as ‘performing tasks or activities of daily living’ and activities that can be labelled as ‘movement activities’ necessary for the performance of ‘activities of daily living’. We labelled these two scales ‘basic movement activities’ (BMA) and ‘activities of daily living’ (ADL).

- One factor within the *participation* component explained 54.3% of the total variance and

included five items. This factor was labelled ‘participation in life situations’ (PLS).

- One factor within the *environmental factors* component explained 40.2% of the total variance and included four items. This factor was labelled ‘environmental factors’ (EF).

Six items were not entered in the factor analysis due to a low prevalence ($\leq 20\%$) [19,30]: limitations in

conversation; limitations in using communication devices; limitations in eating and drinking; limitations in looking after one's health; restrictions in the environment in using communication devices and restrictions in acquiring a place to live. Another six items were excluded from scale construction because of insufficient or dual factor loadings: impairment in speech functions, fatigue, pain, impairment in seeing functions, limitations in moving around using equipment (e.g., wheelchair) and limitations in using transportation.

Single items

Four items excluding items with a high prevalence were added to the questionnaire as single 'symptom' items as clinically important symptoms in MS (see introduction): fatigue, pain, impairment in seeing functions and impairment in speech functions.

Reliability

The internal consistency of five MSIP scales was good (Table IV): Cronbach's alpha ranged from 0.80 to 0.91 and mean inter-item correlation (MIIC) ranged from 0.46 to 0.65. The 'mental functions' scale's Alpha was 0.62, which was, given the number of items and strong MIIC (0.35), sufficient. Cronbach's alpha of the 'environmental factors' scale was weak (0.49), but its MIC was sufficient (0.19) which fits the expectations for this broad construct. Since the MICC was sufficient, we decided to include the environmental factors scale in the MSIP.

The final version of the MSIP consists of 36 items (seven scales with 32 items and four single items: see Appendix). Validity was examined with this 36-item version.

Convergent and discriminant validity

Table V provides evidence of convergent and discriminant validity of the MSIP scales reflecting the impact of multiple sclerosis on physical, psychological and social aspects of functioning. The direction, magnitude and pattern of correlations are consistent with predictions. For example, convergent validity is supported by the strong correlation values between the MSIP physical functioning scales (MMF, BMA and ADL) and the SF-36 'physical functioning' scale, the DIP 'mobility' scale and GARS 'ADL' and 'IADL' scales. Similarly, the MSIP 'participation in life situations' scale correlates highly with the DIP 'social activities' scale. Convergent validity is supported by weak correlation values found between the MSIP 'mental functions' scale and the SF-36 'physical functioning' scale, and the GARS 'activities' scales. Similarly, the MSIP 'participation in life situations' scale correlates weakly with the MSIP 'mental functioning' scale and the SF-36 'mental health' scale. Notably, convergent validity for the MSIP 'mental functions' scale with the similar 'mental functioning' scales was moderate despite higher correlation values being expected. Divergent validity for the MSIP 'participation in life situations' scale with physical functioning scales was moderate despite lower correlation values being expected. Expectations for mono-method effects were supported in all aspects of functioning: convergent and discriminant correlation values between MSIP scales were higher than correlation values between MSIP scales and scales of concurrent measures. Unexpected were the relatively strong correlation values found between the MSIP scales and GARS scales. As hypothesized, the MSIP environmental scale showed weak correlations with all physical, psychological and social functioning

Table IV. Scale and symptom item features of the MSIP.

	Cases (<i>n</i>)	Items (<i>k</i>)	Possible score range	Obs. score range	Mean	SD	Cronbach's α	MIIC*
<i>MSIP scales</i>								
Muscle and Movement Functions (MMF)	451	4	0–16	0–16	4.9	3.4	0.88	0.65
Excretion and Reproductive Functions (ERF)	441	3	0–12	0–12	3.6	3.0	0.80	0.54
Mental Functions (MF)	431	3	0–12	0–12	2.6	2.0	0.62	0.35
Basic Movement Activities (BMA)	536	5	0–15	0–15	4.8	4.6	0.90	0.64
Activities of Daily Living (ADL)	503	8	0–24	0–24	8.3	7.2	0.91	0.56
Participation in Life Situations (PLS)	502	5	0–20	0–18	2.9	3.5	0.81	0.46
Environmental Factors (EF)	318	4	0–16	0–16	3.5	2.7	0.49	0.19
<i>MSIP symptom items</i>								
Speech functions	586	1	0–4	0–4	0.3	0.6	–	–
Fatigue	573	1	0–4	0–4	2.0	1.0	–	–
Pain	569	1	0–4	0–4	1.0	1.0	–	–
Seeing functions	566	1	0–4	0–4	0.8	0.9	–	–

*MICC, mean inter-item correlation.

Table V. Convergent and discriminant validity of the MSIP.

	Body functions			Activities		Participation	Environmental Factors	
	MMF	ERF	MF	BMA	ADL	PLS	EF	Alpha
<i>MSIP</i>								
Muscle and Movement Functions	1							0.88
Excretion and Reproductive Functions	0.66	1						0.78
Mental Functions	0.62	0.40	1					0.62
Basic Movement Activities	0.78	0.65	0.30	1				0.90
Activities of Daily Living	0.76	0.68	0.30	0.89	1			0.91
Participation in Life Situations	0.59	0.58	0.37	0.70	0.71	1		0.81
Environmental factors	-0.14	-0.14	0.13	-0.13	0.04	0.12	1	0.49
<i>SF-36</i>								
Physical Functioning	-0.73	-0.57	-0.27	-0.77	-0.78	-0.61	0.03	0.96
Role Physical	-0.46	-0.40	-0.50	-0.44	-0.48	-0.48	0.03	0.86
Bodily Pain	-0.44	-0.34	-0.49	-0.44	-0.49	-0.42	-0.05	0.91
General Health	-0.31	-0.32	-0.46	-0.36	-0.35	-0.36	-0.13	0.79
Mental health	-0.23	-0.21	-0.52	-0.18	-0.29	-0.39	-0.26	0.86
Role Emotional	-0.27	-0.22	-0.47	-0.25	-0.31	-0.45	-0.21	0.90
Social Functioning	-0.41	-0.40	-0.60	-0.43	-0.56	-0.48	-0.12	0.81
Vitality	-0.38	-0.35	-0.45	-0.33	-0.35	-0.38	-0.09	0.74
<i>DIP</i>								
Mobility	0.76	0.66	0.40	0.84	0.80	0.62	0.02	0.92
Self Care	0.72	0.70	0.45	0.80	0.81	0.63	0.14	0.89
Social Activities	0.61	0.64	0.53	0.72	0.77	0.73	0.22	0.84
Communication	0.50	0.50	0.51	0.60	0.61	0.55	0.11	0.75
Psychological Status	0.31	0.32	0.62	0.41	0.44	0.51	0.21	0.75
<i>WHOQOL-BREF</i>								
Physical Health and Autonomy	-0.64	-0.53	-0.60	-0.58	-0.60	-0.57	-0.02	0.80
Psychological Health	-0.38	-0.37	-0.57	-0.37	-0.38	-0.42	-0.19	0.80
Social Relations	-0.33	-0.45	-0.33	-0.33	-0.35	-0.38	-0.17	0.63
Environment	-0.39	-0.30	-0.40	-0.42	-0.42	-0.47	-0.30	0.81
<i>GARS</i>								
Activities of Daily Living	0.75	0.66	0.18	0.92	0.93	0.67	-0.17	0.97
Instrumental Activities of Daily Living	0.74	0.64	0.29	0.85	0.87	0.66	-0.18	0.95
<i>IPAQ</i>								
Autonomy Indoors	0.64	0.64	0.39	0.73	0.72	0.66	0.04	0.94
Family Role	0.51	0.51	0.42	0.52	0.54	0.53	0.09	0.91
Autonomy Outdoors	0.68	0.68	0.42	0.67	0.71	0.69	-0.03	0.89
Social Relations	0.50	0.50	0.44	0.50	0.48	0.52	0.06	0.86

MMF, Muscle and Movement Functions; ERF, Excretion and Reproductive Functions; MF, Mental Functions; BMA, Basic Movement Activities; ADL, Activities of Daily Living; PLS, Participation in Life Situations; EF, Environmental Factors.

MSIP: $n = 318 - 547$; SF-36: $n = 170 - 171$; DIP: $n = 142 - 147$; WHOQOL-BREF: $n = 490 - 511$; GARS: $n = 369 - 373$; IPA: $n = 364 - 374$.

Italic correlations = expected convergent correlations. Underlined correlations = expected discriminant correlations.

scales of the MSIP and concurrent measures, which supports divergent validity. Convergent validity was not supported: the correlation value with the generic WHOQOL-BREF environmental scale was weak.

Known-groups validity

Known-groups validity of MSIP is supported by confirmed expectations for group differences (Table VI). Patients classified as having progressive MS had statistically significantly higher scores on MSIP scales compared with those classified as having relapsing remitting MS. Identical results were found between patients with a 'higher' or 'lower' extent of limitation. Effect sizes indicating clinical relevance were high or very high. However, the effect size for

mental function between subgroups was moderate. In contrast with these scales, patients with progressive MS or high extent of limitations showed relatively statistically significant lower mean scores on the environmental factors scale.

Discussion

The aim of this study was to develop an ICF-based measure for the impact of MS, and to test the structure, reliability and validity of this measure, which we called the MSIP. The challenge in the development of the MSIP was to examine the applicability of the ICF. Based on the results in this study we conclude that the ICF can play an important role in measurement development and can

Table VI. Known-groups validity of the MSIP.

	Relapsing remitting MS (rr-MS) versus progressive MS (p-MS)				Low (1–4) versus high (5–10) extent of limitations			
	rr-MS: Mean (SD)	p-MS: Mean (SD)	p-value	ES*	Low: mean (SD)	High: Mean (SD)	p-value	ES*
<i>MSIP</i>								
Muscle and Movement Functions (MMF)	2.1 (2.5)	6.2 (3.2)	.00	1.35	2.0 (2.0)	6.2 (3.2)	.00	1.46
Excretion and Reproductive Functions (ERF)	2.1 (2.4)	4.5 (3.0)	.00	0.84	1.9 (2.0)	4.4 (3.0)	.00	0.93
Mental Functions (MF)	2.0 (1.8)	2.9 (2.1)	.01	0.41	1.8 (1.8)	2.9 (2.0)	.00	0.57
Basic Movement Activities (BMA)	1.9 (3.3)	6.2 (4.7)	.00	1.00	1.2 (1.8)	6.3 (4.6)	.00	1.27
Activities of Daily Living (ADL)	3.3 (4.8)	10.7 (7.3)	.00	1.11	2.4 (3.0)	10.8 (7.0)	.00	1.36
Participation in Life Situations (PLS)	1.4 (2.6)	4.6 (4.6)	.00	0.80	0.9 (1.8)	4.8 (4.6)	.00	0.98
Environmental Factors (EF)	5.0 (3.5)	3.2 (3.3)	.00	0.54	4.7 (4.0)	3.3 (3.4)	.02	0.40

improve a unified and standard language in clinical practice and research.

Results regarding the structure of the MSIP show that the original 44-item version could be reduced to 36 items covering seven domains of four ICF components: ‘muscle and movement functions’ (MMF), ‘excretion and reproductive functions’ (ERF) and ‘mental health’ (MH) for the *body functions* component; ‘basic movement activities’ (BMA) and ‘activities of daily living’ (ADL) for the *activities* component; ‘participation in life situations’ (PLS) for the *participation* component; and ‘environmental factors’ (EF) for the *environmental factors* component. Four clinically relevant items were applied as single ‘symptom items’ in the questionnaire: impairment in speech functions, fatigue, pain, and impairment in seeing functions (see final 36-item version in the Appendix). The scales of the reduced version are internally consistent. Reliability of the ‘environmental factors’ scale was sufficient taking into account that the Cronbach’s alpha was low (0.49) and the mean inter-item correlation was sufficient (0.19) for a broad construct as the environmental factors construct is [18].

Analysis of the convergent, discriminant and known-groups validity indicated that the MSIP measures the physical, psychological and social impact of MS and discriminates between categories of disease course and disease severity. The disease-specific environmental factors scale correlated weakly with the concurrent generic environmental scale. This weak association may be explained by the MSIP measuring a much broader environmental construct than the WHOQOL-BREF. Furthermore, patients with progressive MS or high extent of limitations showed statistically significant lower mean scores on the environmental factors scale than patients with relapsing remitting MS or low extent of limitations. This scale thus seems to be sensitive for the relatively smaller need for support from social and health services in the latter group.

This study showed some unexpected results. We were somewhat surprised by the moderate correlations for the MSIP ‘mental functioning’ scale with similar psychological functioning scales indicating weak convergence. The same moderate correlations were found between the psychological functioning scales in the concurrent measures (not in table). Analysing the content of the scales supports this hypothesis: some items are found in each psychological functioning scale (e.g., mood and happiness) while other items were specific to a measure (e.g., nervousness, concentration and self-esteem). These findings may be due to psychological functioning covering a rather broad construct, including some cognitive functions as well. Also unforeseen were the moderate correlations between the MSIP ‘participation in life situations’ scale and the ‘physical functioning’ scales, where lower correlations were expected. This is acceptable when bearing in mind two explanations: moderate correlations indicate related but distinct domains; and, it is reasonable to expect persons who are limited in physical functioning (e.g., changing body position, transferring themselves or walking) will encounter problems in participation in social activities (e.g., visiting family, employment, recreation). The relatively strong correlations between the MSIP scales and GARS scales, which did not support the expected ‘mono-method’ effect, can be explained by the relatively large number of items in the activity scales.

The effect sizes as estimated for known-groups difference for the MSIP ‘mental function’ scale were moderate in the face of higher expected effect sizes. The same results were observed for the concurrent measures (not in table). Apparently, this finding suggests that the impact of multiple sclerosis on mental function is not as great as on physical and social functioning.

The ICF proved to be a useful classification for selecting items and it turned out to be useful in an interdisciplinary setting [8]. Operationalization of

these items to estimate the patients' objectified opinion of the incidence and severity of disabilities was a complicated process. Especially the application of the qualifiers for each ICF component into understandable response options that meet measurement requirements was complex. Considering the results of this study, we think that the qualifiers are applied in an adequate way.

Future studies with the MSIP should evaluate stability over time and responsiveness in intervention studies. Evaluations in different settings will define the role of MSIP in clinical practice and research.

Comparison with disease-specific multiple sclerosis measures, such as the Multiple Sclerosis Impact Scale (MSIS-29) [31], the Functional Assessment of Multiple Sclerosis (FAMS) [32] and the Multiple Sclerosis Quality of Life (MSQoL-54) [33] are necessary. 'These studies may determine advantages and disadvantages of different instruments, how they complement each other, and provide an evidence-based framework to guide the selection of outcome measures for research and clinical evaluation in Multiple Sclerosis' [31].

This study has important implications for clinical trials and epidemiological studies. The MSIP can be used in cross-sectional studies to describe the impact of multiple sclerosis on functional health. Furthermore, the availability of reliable and valid outcome measures with a broad scope like the MSIP is crucial for improved understanding of the impact of MS and its relationship with other indicators of disease activity, such as neuroimaging and neurophysiology.

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Appendix

Multiple Sclerosis Impact Profile (MSIP) (final 36-item version).

MSIP		Body functioning questions
Scale		<i>Response options</i>
		0 = no, not at all; 1 = yes, I have a slight impairment; 2 = yes, I have a moderate impairment; 3 = yes, I have a severe impairment; 4 = yes, I have a complete impairment
MMF	B1	Do you face loss of your <i>muscle power functions</i> ? (b730)
MMF	B2	Do you face <i>muscle stiffness or muscle spasm</i> ? (b7800/b7801)
MMF	B3	Do you face <i>involuntary movements</i> ? (e.g., tremors or tics) (b765)
MMF	B4	Do you face decreased <i>control and co-ordination of your movements</i> ? (b760)
ERF	B5	Do you face impairment in your <i>defecation functions</i> ? (e.g., changes in frequency, constipation, incontinence) (b525)
ERF	B6	Do you face impairment in your <i>urination functions</i> ? (e.g., frequency of urination, incontinence, difficulties with urination) (b620)
ERF	B7	Do you face limitations in <i>sexual relations</i> ? (b640)
MF	B8	Do you face <i>changes</i> in your <i>mental functions</i> ? (e.g., the ability to think logically, the ability to memorise, the ability to concentrate) (b160/b144/b140)
MF	B9	Do you face <i>changes</i> in your <i>emotional functions</i> ? (e.g., fear, depression, happiness) (b152)
MF	B10	Do you face impairment in your <i>sleep functions</i> ? (e.g., onset of sleep, the maintenance of sleep or the quality of sleep) (b134)
SYMP	B11	Do you experience <i>fatigue</i> ? (e.g., decreased energy and endurance) (b1300/b455)
SYMP	B12	Do you experience <i>pain</i> ? (b280)
SYMP	B13	Do you face impairment in your <i>speech functions</i> ? (b320)
SYMP	B14	Do you face impairment in your <i>seeing functions</i> ? (with spectacles on or lenses in) (b210)
		Activities questions
		<i>Response options</i>
		0 = No
		1 = Yes, but assistance devices and/or adaptations <i>are not</i> necessary
		2 = Yes, and assistance devices and/or adaptations <i>are</i> necessary
		3 = Yes, and assistance devices and/or adaptations <i>and</i> another person's help are necessary.
BMA	A1	Do you face limitations in <i>maintaining your body position</i> ? (e.g., maintaining a kneeling, standing and sitting postures) (a415)
BMA	A2	Do you face limitations in <i>changing your body position</i> ? (e.g., moving from lying down to standing up or from standing to sitting) (a410)
BMA	A3	Do you face limitations in <i>transferring yourself</i> ? (e.g., moving from a chair into bed; from a wheelchair into a car) (a420)
BMA	A4	Do you face limitations in your <i>fine hand use</i> ? (e.g., picking up small objects; manipulating a keyboard) (a440)
BMA	A5	Do you face limitations in your <i>arm(s) and hand(s) use</i> ? (e.g., pulling or pushing objects; turning or twisting knobs or handles; reaching for kitchen cupboard) (a445)
ADL	A6	Do you face limitations in <i>walking</i> ? (a450)
ADL	A7	Do you face limitations in <i>washing yourself</i> ? (a510)
ADL	A8	Do you face limitations in <i>caring for parts of your body</i> ? (e.g., brushing teeth, clipping your nails, combing your hair, shaving) (a520)
ADL	A9	Do you face limitations in <i>dressing yourself</i> ? (a540)
ADL	A10	Do you face limitations in <i>preparing meals</i> ? (a630)
ADL	A11	Do you face limitations in <i>toileting</i> ? (a530)
ADL	A12	Do you face limitations in <i>doing housework</i> ? (a640)
ADL	A13	Do you face limitations in activities you would like to undertake for <i>recreation or leisure</i> ? (a920)
		Participation questions
		<i>Response options</i>
		0 = no
		1 = Yes, as a consequence I have <i>some</i> trouble with . . .
		2 = Yes, as a consequence I have trouble with . . .
		3 = Yes, as a consequence I have <i>a lot of</i> trouble with
		4 = Yes, as a consequence . . . is (nearly) impossible.
PLS	P1	Are there <i>obstacles</i> in your <i>environment</i> that complicate your <i>mobility inside or outside your home</i> ? (e.g., thresholds; curbs; absence of elevators) (p460/p470)

(continued)

(Continued)

PLS	P2	Are there <i>obstacles in your environment</i> that complicate your <i>personal care</i> ? (e.g., you do not have the necessary assistance devices and adaptations at your disposal) (p510-p540/p630)
PLS	P3	Are there <i>obstacles in your environment</i> that complicate the <i>maintenance of your relationships with your closest family, friends or relatives</i> ? (e.g., the travel distance, the attitude of others) (p740-p760)
PLS	P4	Are there <i>obstacles in your environment</i> that complicate your participation in <i>employment</i> ? (e.g., an unadapted workplace, the attitude of colleagues and/or the manager) (p850)
PLS	P5	Are there <i>obstacles in your environment</i> that complicate your participation in <i>community, recreation and leisure</i> ? (e.g., accessibility of clubs or associations) (p910/p920)
Environmental Factors questions		
<i>Response options</i>		
0 = Yes, very supportive		
2 = Yes, somewhat supportive		
4 = No, not supportive		
EF	EF1	Is your relationship with your <i>immediate family</i> supportive to you? (e.g., partner, children, parents, brothers, sisters) (e310)
EF	EF2	Is the <i>professional care and assistance</i> you receive supportive to you? (e.g., unpaid care and assistance included) (e340)
EF	EF3	Are the <i>social security services</i> supportive to you? (e.g., income support) (e570)
EF	EF4	Are the <i>health services</i> supportive to you? (e.g., medical and nursing care) (e580)

MMF, Muscle and Movement Functions; ERF, Excretion and Reproductive Functions; MF, Mental Functions; BMA, Basic Movement Activities; ADL, Activities of Daily Living; PLS, Participation in Life Situations; EF, Environmental Factors.